

STATUS OF THE CLAIMS

Claims 1-29 are pending herein, claims 1 and 21 being the independent claims. Claims 24-29 have been withdrawn pursuant to a restriction requirement. Applicants hereby amend independent claims 1 and 21 and have added new dependent claims 30 and 31. Support for the amendment to claims 1 and 21 is provided, *inter alia*, in paragraph [0026] of the specification and the original filed claims. Support for the amendments to dependent claims 6, 7, 9-11, 13-16, and 18-20 is provided in the original claims as filed. Support for new dependent claims 30 and 31 is provided, *inter alia*, in paragraph [0026], lines 2, 4, and 5. Applicants state that there is no issue of new matter.

Applicants acknowledge that the Examiner has withdrawn the previous rejections over Sawhney et al. and have rendered the new grounds of rejection discussed below.

Rejection Under 35 U.S.C. § 112, second paragraph

Claim 21 is rejected for not providing an antecedent basis for the plural term “polymers” in line 1.

In response, Applicants have corrected claim 21 such that the term “polymers” has been replaced with the singular, “polymer.” Thus, Applicants state that the amendment to claim 21 obviates the rejection.

Rejection under 35 U.S.C. §102(b) or §103(a) – Weikel et al. in view of Trieu

Claims 1-9, 11-14, 16, 18, and 19 are rejected under 35 U.S.C. 102(b) as anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over Weikel et al. (U.S. Patent No. 6,632,235) in view of Trieu (U.S. Appln. Pub. No. 2004/0186471).

In response, Applicants respectfully traverse the rejections over Weikel et al. Applicants submit that the amendment of independent claims 1 and 21 has rendered the rejection moot. The invention of the claims, as amended, is neither anticipated by nor rendered unpatentable in light of the disclosures of Weikel et al. As amended, independent claims 1, from which the remainder of the rejected claims depend, is directed to the following (emphasis added):

1. A method of providing a therapeutic agent-containing polymeric body within a subject, said method comprising:

- (a) injecting a first fluid comprising a polymer which further comprises a therapeutic agent into a container that is positioned within the subject;
 - (b) injecting a ***second fluid comprising a crosslinkable polymer into said container, said second fluid having a lower viscosity than said first fluid and wherein said second fluid coats said first fluid;***
 - (c) crosslinking said crosslinkable polymer in said container by introducing a crosslinking agent to said container, thereby forming a crosslinked polymeric body comprising a ***first fluid coated with a crosslinked polymer in said container;*** and
 - (d) releasing said crosslinked solid polymeric body into said subject.
- (emphasis added).

The Weikel et al. reference fails as an anticipatory reference because it fails to teach all of the claimed features of independent claims 1 and 21, as amended. For a reference to anticipate a claim it ***must disclose each and every element of the claim***. See MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978).

Specifically, neither Weikel et al. nor Trieu teach or suggest the following claim features that are found in both independent claims 1 and 21, as amended, either explicitly or inherently:

- (1) injecting a ***second fluid comprising a crosslinkable polymer into said container, said second fluid having a lower viscosity than said first fluid and wherein said second fluid coats said first fluid;***
- (2) forming a crosslinked solid polymeric body comprising a ***first fluid coated with a crosslinked polymer in said container***

Neither Weikel et al. nor Trieu teach the injection of a second fluid comprising a crosslinkable polymer into said container. Neither Weikel et al. nor Trieu teach that the second fluid has a lower viscosity than the first fluid. Neither Weikel et al. nor Trieu teach a second fluid that coats said first fluid. Neither Weikel et al. nor Trieu teach a solid polymer body comprising a first fluid coated with a crosslinked polymer in said container.

Since Weikel et al. fails as an anticipatory reference, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection over Weikel et al. Independent claim 1 has been rejected and the remainder of the rejected claims depend directly on claim 1 and contain additional distinguishing features. The rejection of those claims fails at least because of the fundamental defect discussed above with respect to independent claim 1.

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The Examiner has also rejected the claims stating that they are obvious in light of the disclosures of Weikel et al. in view of Trieu.

In response, Applicants respectfully traverse the obviousness rejection over Weikel et al. in view of Trieu and state that the Examiner has failed to establish a *prima facie* case of obviousness. The combined references fail to teach all of the features of the claimed invention. Neither Weikel et al. nor Trieu teach the injection of a second fluid comprising a crosslinkable polymer into said container. Neither Weikel et al. nor Trieu teach that the second fluid has a lower viscosity than the first fluid. Neither Weikel et al. nor Trieu teach a second fluid that coats said first fluid. Neither Weikel et al. nor Trieu teach a solid polymer body comprising a first fluid coated with a crosslinked polymer in said container. Given such deficiency in the cited art, Applicants respectfully state that the burden of establishing a *prima facie* of obviousness has not been met and requests that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. 103(a).

The Examiner's failure to show how the combined references teach or suggest each and every feature of a claim is fatal to an obviousness rejection under 35 U.S.C. § 103, despite any recent revision to the Manual of Patent Examining Procedure (MPEP). Applicants draw the Examiner's attention to Section 2143.03 of the MPEP which requires the "consideration" of every claim feature in an obviousness determination. To render claim 1 unpatentable, however, the Office must do more than merely "consider" each and every feature for this claim. Instead, the asserted prior art must also teach or suggest ***each and every claim feature***. See *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) (emphasis added) (to establish *prima facie* obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art). Indeed, as the Board of Patent Appeal and Interferences has recently confirmed, a proper obviousness determination requires that an Examiner make "a searching comparison of the claimed invention - *including all its limitations* - with the teaching of the prior art." See *In re Wada and Murphy*, Appeal 2007-3733, citing *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis in original).

Further, the necessary presence of all claim features is axiomatic, since the Supreme Court has long held that obviousness is a question of law based on underlying factual inquiries,

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including ... ascertaining the differences between *the claimed invention* and the prior art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) (emphasis added). Further, it remains well-settled law that obviousness requires at least a suggestion of all of the features in a claim. *See In re Wada and Murphy*, citing *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) and *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Such “suggestion” of the claimed elements is lacking from any of the cited references, which provides no teaching or suggestion of ***a second fluid of lower viscosity which coats the first fluid to form a crosslinked solid polymeric body comprising a first fluid coated with a crosslinked polymer in said container.*** Such structure is simply not taught or suggested.

Applicants respectfully state that the Examiner has neither met his burden of establishing a *prima facie* case of obviousness nor provided a rational underpinning to support her legal conclusion of obviousness. Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in, KSR Int’l v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740-41, 82 USPQ 1385, 1396 (2007).

Since the Weikel et al. reference, either singly or in combination with the secondary references, fails to establish a *prima facie* case of obviousness, reconsideration and withdrawal of the rejection as being unpatentable over the cited art, is therefore requested. Claim 1 is the sole independent claim in this rejection, and the above comments apply directly to this claim. All other rejected claims are dependent directly on claim 1 and the rejection of those claims fails at least because of the fundamental defect discussed above and further because of additional distinguishing features present in those dependent claims.

Rejection under 35 U.S.C. §102(b) or §103(a) – Weikel et al. in view of Trieu in view of Spacek

Claim 10 is rejected under 35 U.S.C. §103(a) as obvious over Weikel et al. (U.S. Patent No. 6,632,235) in view of Trieu (U.S. Appln. Pub. No. 2004/0186471) as applied to Claim 1 and further in view of Spacek (U.S. Patent No. 6,524,327).

In response, Applicants respectfully traverse the rejection over Weikel et al. in view of Trieu and Spacek and reiterate the arguments made above, with respect to the rejection of independent claim 1, upon which rejected claim 1 depends. The secondary reference, Spacek does not remedy the deficiencies of Weikel et al. and/or Trieu. As the Examiner states, “Spacek discloses a method for forming a solid polymeric body in situ and teaches once the crosslinking, or bonding is complete, the polymeric body should be washed to remove unreacted reactants and any byproducts to ensure biocompatibility.” Spacek does not teach the injection of a second fluid comprising a crosslinkable polymer into said container. Spacek does not teach that the second fluid has a lower viscosity than the first fluid. Spacek does not teach a second fluid that coats said first fluid. Spacek does not teach a solid polymer body comprising a first fluid coated with a crosslinked polymer in said container.

Since the Weikel et al. reference, either singly or in combination with the secondary references, fails to establish a *prima facie* case of obviousness, reconsideration and withdrawal of the rejection as being unpatentable over the cited art, is therefore requested. Claim 10 is the sole claim in this rejection, and the above comments regarding the rejection of Claim 1 apply directly to this claim.

Rejection under 35 U.S.C. §102(b) or §103(a) – Weikel et al. in view of Trieu in view of Schwarz

Claims 15, 17, 20-23 are rejected under 35 U.S.C. §103(a) as obvious over Weikel et al. (U.S. Patent No. 6,632,235) in view of Trieu (U.S. Appln. Pub. No. 2004/0186471) as applied to Claim 1 and in view of Schwarz (U.S. Appln. Pub. No. 2005/0008610).

In response, Applicants respectfully traverse the rejections over Weikel et al. Applicants submit that the amendment of independent claims 1 and 21 has rendered the rejection moot. The invention of the claims, as amended, is neither anticipated by nor rendered unpatentable in light of the disclosures of Weikel et al. As amended, independent claim 1, from which the remainder of the rejected claims depend, is directed to the following (emphasis added):

1. A method of providing a solid therapeutic agent-containing polymeric body within a subject, said method comprising:

- (a) injecting a first fluid comprising a polymer which further comprises a therapeutic agent into a container that is positioned within the subject;
 - (b) injecting a ***second fluid comprising a crosslinkable polymer into said container, said second fluid having a lower viscosity than said first fluid and wherein said second fluid coats said first fluid;***
 - (c) crosslinking said crosslinkable polymer in said container by introducing a crosslinking agent to said container, thereby forming a crosslinked polymeric body comprising a ***first fluid coated with a crosslinked polymer in said container;*** and
 - (d) releasing said crosslinked solid polymeric body into said subject.
- (emphasis added).

21. A method of providing a solid polymeric body within a subject, said method comprising: (a) injecting a first fluid comprising a first polymer into a container that is positioned within the subject, (b) injecting a ***second fluid comprising a crosslinkable polymer into said container, said second fluid having a lower viscosity than said first fluid and wherein said second fluid coats the first fluid;*** (c) crosslinking said crosslinkable second polymer[[s]] in said container by introducing a crosslinking agent to said container, thereby forming a crosslinked polymeric body comprising a ***first fluid coated with a crosslinked polymer in said container;*** and (d) releasing said crosslinked solid polymeric body into said subject.

(emphasis added).

In response, Applicants respectfully traverse the rejection over Weikel et al. in view of Trieu and Schwarz et al. and reiterate the arguments made above, with respect to the rejection of independent claim 1. The secondary reference, Schwarz et al. does not remedy the deficiencies of Weikel et al. and/or Trieu. As the Examiner states, “Schwarz et al. discloses a similar method for forming a solid polymeric body in situ comprising injecting a fluid crosslinkable polymer and crosslinking the polymer within the body.”

Applicants state that the amendments to independent claims 1 and 21, have rendered the rejection moot. The combination of references fails to teach a “***second fluid comprising a crosslinkable polymer into said container, said second fluid having a lower viscosity than said first fluid and wherein said second fluid coats the first fluid.***” The combination also fails to teach forming a crosslinked polymeric body comprising a ***first fluid coated with a crosslinked polymer in said container.***

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Since the Weikel et al. reference, either singly or in combination with the secondary references, fails to establish a *prima facie* case of obviousness, reconsideration and withdrawal of the rejection as being unpatentable over the cited art, is therefore requested. Independent claim 21 has been rejected. The rejection of that claim as well as the remainder of the claims which depend upon either claim 1 or 21 fails at least because of the fundamental defect discussed above with respect to claim 1 (and which distinguishing features are also in claim 21) and further because of additional distinguishing features present in those dependent claims.

CONCLUSION

In view of the above, Applicant submits that all pending claims are in condition for allowance. If the Examiner believes there are still unresolved issues, a telephone call to the undersigned would be welcomed.

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Respectfully submitted,

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